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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,006	09/10/2001	Felix Montero Julian	JULIAN-1	1262
1444	7590	10/04/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			LAM, ANN Y	
624 NINTH STREET, NW			ART UNIT	
SUITE 300			PAPER NUMBER	
WASHINGTON, DC 20001-5303			1641	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,006

Applicant(s)

MONTERO JULIAN ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-16 and 19 is/are rejected.
- 7) ☒ Claim(s) 17 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for monoclonal antibodies produced from hybridoma I-2068, does not reasonably provide enablement for use of other monoclonal antibodies in the method of claims 1-10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Except for the monoclonal antibodies produced from hybridoma I-2068, the specification does not teach any other monoclonal antibody that has the properties of not interfering with the fixing of IL-5 to its receptor and does not inhibit the biological activity of IL-5. Thus, the specification only provides enablement for monoclonal antibodies from hybridoma I-2068 as opposed to any other monoclonal antibodies. The claims are not limited to the monoclonal antibodies from hybridoma I-2068 and thus the scope of the claims are not enabled by the specification.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – the invention is directed toward an anti-IL-5R antibody which does not interfere with the fixing of IL-5 to its receptor and which does not inhibit the biological activity of IL-5.

The predictability or lack thereof of in the art – it is not predictable that any monoclonal antibody, other than those produced from hybridoma I-2068, will not interfere with the fixing of IL-5 to its receptor and does not inhibit the biological activity of IL-5.

The amount of direction or guidance present – no guidance is available to teach a skilled artisan an anti-IL5-receptor monoclonal antibody, other than those produced from hybridoma I-2068, which does not interfere with the fixing of IL-5 to its receptor and which does not inhibit the biological activity of IL-5. The instant specification fails to disclose the manner in which monoclonal antibodies are generated with the required properties recited in the instant claim 1. The only monoclonal antibodies with the required properties are those generated from hybridoma I-2068.

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The presence or absence of working examples – there is no working example in the specification of monoclonal antibodies, other than those produced from hybridoma I-2068, which does not interfere with the fixing of IL-5 to its receptor and which does not inhibit the biological activity of IL-5.

The quantity of experimentation necessary – it would be undue experimentation for a skilled artisan to make and use the inventions as claimed since not all monoclonal antibodies will not interfere with the fixing of IL-5 to its receptor and will not inhibit the biological activity of IL-5.

The relative skill of those in the art – the level of skill in the art is high.

The breadth of the claims – the claims do not limit the method to use of monoclonal antibodies from hybridoma I-2068.

In summary, the specification does not teach how a monoclonal antibody, except those from hybridoma I-2068, will not interfere with the fixing of IL-5 to its receptor and does not inhibit the biological activity of IL-5. Thus, the specification only provides enablement for monoclonal antibodies produced from hybridoma I-2068 that will not interfere with the fixing of IL-5 to its receptor and does not inhibit the biological activity of IL-5, and does not provide enablement for the other monoclonal antibodies. The instant specification lacks sufficient guidance to enable one of ordinary skill in the art to produce other monoclonal antibodies with properties required in instant claim 1. Since the claims are not limited to monoclonal antibodies produced from hybridoma I-2068, the scope of the claims are not enabled by the specification. Thus, based on the limited disclosure of the specification and the breadth of the claims, the specification is

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only enabled for monoclonal antibodies from hybridoma I-2068, but not for any other monoclonal antibodies.

Claim Rejections - 35 USC § 112

Claims 1-4, 6-10, 16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-10 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: labels for the detecton of eosinophils or basophils. (It does not appear to be possible to detect eosinophils or basophils without a label or stain.)

Allowable Subject Matter

Claims 1-4, 6-10, 16 and 19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 18 is allowed

Response to Arguments

In view of the amendment to the specification adding the address of the depository and Applicant's submission of declaration of biological material deposit, the enablement rejection in the previous Office action for failure to make hybridoma-I-2068 known and readily available to the public or obtainable by a repeatable method has been withdrawn.

Applicant's arguments with respect to claims 11-15 are persuasive and therefore the previous art rejection has been withdrawn. However, upon reconsideration, claims 11-15 are rejected for exceeding the scope of enablement as described above.

With respect to the previous rejections of claims 5-8 under 112, second, the rejections are withdrawn in view of Applicant's arguments as to the purpose of these other markers, as well as cancellation of claim 5 (the content of which now appears to be in new claim 19, with clarified language.)

With respect to whether claims 1-4, 6-10 and 16 require a label, Applicant's arguments are not persuasive. Applicant argues that a label is not required in claim 1 because it is possible to use conventional methods that physically trap the bound antibodies (for example chromatography column) to isolate eosinophils and/or basophils and that such well known methods do not require labeling the antibody. This is not persuasive because although such methods may trap antibodies and thus isolate eosinophils and/or basophils, the eosinophils and/or basophils still need to be detected. It is not clear how they

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can be detected without a label or stain. Thus, it appears that an essential element is omitted, as described above.

Applicant's argument with respect to claims 9 and 10 are persuasive and thus the rejection under 112, second has been withdrawn.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/30/05